

REMARKS/ARGUMENTS

Initially, Applicants would like to express their appreciation to the Examiner for the detailed Official Action provided.

Applicants submit that the instant amendment is proper for entry after final rejection. Applicants note that no question of new matter or any new issues are raised in entering the instant amendment of the claims and that no new search would be required.

Moreover, Applicants submit that the instant amendment places the application in condition for allowance, or at least in better form for appeal.

Accordingly, Applicants request that the Examiner enter the instant amendment, consider the merits of the same, and indicate the allowability of the present application and each of the pending claims.

Upon entry of the above amendments claims 1, 2, 3 and 5 will have been amended. Claims 1-10 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

In the Official Action, the Examiner has maintained the rejection of claims 1, 3 and 7-10 under 35 U.S.C. § 102(b) as being anticipated by HIPPS (U.S. Patent No. 2,543,780).

Without acquiescing to the propriety of the Examiner's rejection, Applicants have amended independent claim 1 solely in order to expedite prosecution of the present application. In this regard, Applicants note that HIPPS fail to teach or suggest the combination of elements as recited in claim 1.

In particular, claim 1 sets forth a device for ligament reconstruction including, inter alia, a rear-end having at least two rear-end through-holes extending in juxtaposition coaxially with the through-holes formed in said tip and body, wherein said tip and body has either one of a uniform generally elliptical or generally rectangular cross section elongated in a direction in which the through-holes thereof are juxtaposed, said rear-end being configured to drive said tip and body into a bone which receives ligament reconstruction.

Applicants submit that HIPPS lacks any disclosure of at least the above noted combination of elements.

In setting forth the rejection, the Examiner asserts that HIPPS discloses the presently claimed ligament reconstruction device. However, contrary to the Examiner's assertions, HIPPS discloses a bone grafting apparatus which is structurally very different from the presently claimed ligament reconstruction device.

More particularly, HIPPS discloses a bone site shell 20 extending through a fleshy part of a thigh "C" and contacting a femur "B" (see, Col. 2, lines 3-6-44). Further, a bone drill guide (see, FIG. 6) having four drill guide tubes 37, held and spaced by circular plates 38, may be inserted into the shell 20 (see, Col. 3, lines 20-24). Subsequently, a bone drill 41 having a long shank 42 is inserted into the guide tubes 37 and operated so that holes are drilled in the bone (see, FIG. 13). In other words, the drill guide tubes 37 and circular plates 38, as disclosed in HIPPS, at most, contact a surface of the bone "B" in order to guide the shank 42 which performs the actual drilling. That is, the portions of the bone drill guide (i.e., which the Examiner considers to be the tip and body), as disclosed in HIPPS, do not, and are not configured to, penetrate the surface of the bone.

Thus, HIPPS does not disclose at least the presently claimed rear-end being configured to drive the tip and body into a bone which receives ligament reconstruction.

Applicants note that “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” See, In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004).

Additionally, in regard to the Examiner’s rejection of method claims 8-10, as discussed *supra*, HIPPS does not discloses at least the presently claimed driving the tip and body of the device for ligament reconstruction into a bone and reconstruct a ligament, and is therefore, incapable of performing the method recited in claims 8-10.

Applicants further note, that “[a]bsent a disclosure in a single reference of each and every element recited in a claim, a *prima facie* case of anticipation cannot be made under 35 U.S.C. § 102. Since the applied reference fails to disclose each and every element recited in independent claims 1 and 8, as well as claims 2-7, 9 and 10, depending therefrom, these claims are not anticipated thereby. Further, all pending dependent claims recite additional features that further define the present invention over the prior art. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102 and allow all pending claims in the present application.

In the Official Action, the Examiner has rejected claims 2 and 4-6 under 35 U.S.C. § 103(a) as being unpatentable over HIPPS.

Applicant respectfully traverses the above noted rejection of claims 2 and 4-6 under 35 U.S.C. § 103(a).

Further, Applicants submit that dependent claims 2 and 4-6, are at least patentable due to their dependency from claim 1 for the reasons noted above. In this regard, Applicants note that the Examiner has provided no explanation or motivation for correcting the above-noted deficiencies in the teachings of HIPPS. Applicants further submit that the Examiner's assertion that the combination of elements recited in claims 2 and 4-6, only involve discovering obvious optimum or workable ranges, does not provide any teachings which could reasonably be characterized as curing the above-noted deficiencies in the teachings of HIPPS.

In this regard, Applicants submit that HIPPS does not disclose at least the presently claimed rear-end having at least two rear-end through-holes extending in juxtaposition coaxially with the through-holes formed in the tip and body, wherein the tip and body has either one of a uniform generally elliptical or generally rectangular cross section elongated in a direction in which the through-holes thereof are juxtaposed, the rear-end being configured to drive the tip and body into a bone which receives ligament reconstruction, as recited in amended independent claim 1.

Further, in regard to claims 2 and 4-6, the Examiner acknowledges that HIPPS does not disclose the combination of elements recited therein. Nevertheless, the Examiner asserts that the combination of elements recited therein (*i.e.*, claims 2 and 4-6) only involve discovering obvious optimum or workable ranges. However, Applicant submits that the Examiner has provided no factual evidence to support his assertion.

As discussed in the previous Response, Applicants note that “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

In this regard, Applicants submit that the Examiner still has not made such showing. Although the Examiner asserts that the use of the term “preferable” in the written description somehow indicates that the features recited in claims 2 and 4-6 is not critical. The written description clearly discusses the advantages of the present claimed device for ligament reconstruction.

More particularly, at least one advantage of the presently claimed invention is that the tip and body portion have a generally elliptical or rectangular cross section rather than a simple round cross section. Therefore, the bone cavity to be formed in the bone has a cross section close to the cross section of an ordinary ligament, so that the outer peripheral surface of the ligament is entirely brought into proximity to the interior surface of the bone cavity. Hence, the ligament can be bonded to the bone with a greater bonding force in a shorter period of time (see, Page 2, lines 23-29).

Thus, it is apparent from the present Specification that the particular geometries of the device for ligament reconstruction, as recited in claims 2 and 4-6, will at least have an advantageous effect on ligament bonding.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103 and allow all pending claims in the present application. Further, if the Examiner decides to maintain the aforementioned rejection of claims 2 and 4-6,

Applicants respectfully request that the Examiner provide an appropriate teaching reference disclosing the recited features.

In view of the arguments herein, Applicants submit that independent claim 1 is in condition for allowance. With regard to dependent claims 2-7, 9 and 10, Applicants assert that they are allowable on their own merit, as well as because of their dependency from independent claim 1, which Applicants have shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

SUMMARY

Applicants submit that the present application is in condition for allowance, and respectfully request an indication to that effect. Applicants have argued the allowability of the claims and pointed out deficiencies of the applied reference. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicants note the status of the present application as being an after final rejection and with respect to such status believes that there is a clear basis for the entry of the present amendment consistent with 37 C.F.R. § 1.116. Applicants note amendments after final are not entered as a matter of right; however, Applicants submit that the present amendment does not raise new issues or the question of new matter. Moreover, the present amendment clearly places the present application in condition for allowance.

Applicants note that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
Konsei SHINO et al.

**William Pieprz**  
**Reg. No. 33,630**

  
Bruce H. Bernstein  
Reg. No. 29,027

May 7, 2007  
GREENBLUM & BERNSTEIN, P.L.C.  
1941 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191